K992159

510(K) SUMMARY

Submitted By: Neal E. Fearnot, Ph.D.
President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355
June 23, 1999

Names of Device:

Trade Name:	SURGISIS™ Sling
Common/Usual Name:	Surgical Mesh, Sling, Urethral Sling
Proposed Classification Name:	Surgical Mesh (21 CFR §878.3300)

Predicate Devices:

SURGISIS™ Mesh (K980431) manufactured by Cook Biotech Incorporated
Glycar Staple Strips (K954665) manufactured by Glycar, Incorporated
Mentor Suspend™ Sling (K980483) manufactured by Mentor Corporation
Surgical Fabrics (K963226) manufactured by Boston Scientific

Device Description:

The Surgisis™ Sling is supplied in sheet form in sizes ranging from 20 cm^2 to 140 cm^2. The device is packaged in sterile, sealed double pouches.

Intended Use:

The SURGISIS™ Sling is intended for implantation to reinforce soft tissues where weakness exists in the urological, gynecological, and gastroenterological anatomy including but not limited to the following procedures: pubourethal support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, and sacrocolposuspension. By providing pubourethal support, the SURGISIS™ Sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency. The device is intended for one-time use.

Substantial Equivalence:

The Surgisis™ Sling is substantially equivalent to the predicate devices, having the same intended use and technological characteristics.

Discussion of Tests and Test Results:

The Surgisis™ Sling was subjected to a panel of tests to assess biocompatibility, integrity, and performance. The Surgisis™ Sling passed the requirements of all tests.

Conclusions Drawn from Tests:

This device is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

Neal E. Fearnot, Ph.D.
President
Cook Biotech, Incorporated
3055 Kent Avenue
West Lafayette, Indiana 47906

Re: K992159
Trade Name: SurgiSis™ Sling
Regulatory Class: II
Product Code: FTM
Dated: June 23,1999
Received: June 25, 1999

Dear Dr. Fearnot:

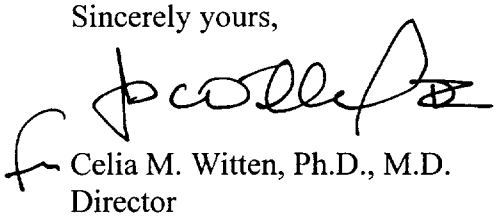
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992159

Device Name: **SURGISIS™ Sling**

Indications For Use:

The SURGISIS™ Sling is intended for implantation to reinforce soft tissues where weakness exists in the urological, gynecological, and gastroenterological anatomy including but not limited to the following procedures: pubourethal support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, and sacrocolposuspension. By providing pubourethal support, the SURGISIS™ Sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency. The device is intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992159

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)